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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/713,780	11/15/2000	Fatih M. Uckun	12152.109US01	3061

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EXAMINER	
PAK, JOHN D	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/713,780	UCKUN, FATIH M.	
	Examiner	Art Unit	
	JOHN D PAK	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-16 and 25-36* is/are pending in the application.

4a) Of the above claim(s) *11-16 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-10,25 and 27-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 4-16 and 25-36 are pending in this application.

Upon reconsideration and further review, allowability of VDacac in the method claims must be rescinded due to the rejections based on 35 USC 112 set forth below. In view of the amendment to claim 4, all of the vanadocene compounds encompassed by claim 4 will presently be examined.

Claims 11-16 and 26 (dependent on claim 16) are withdrawn from further consideration as being directed to non-elected subject matter. Claims 4-10 and 25, 27-36 will presently be examined to the extent that they read on the scope of claim 4 vanadocene compounds.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-10, 25, 27, 32-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(1) The claims rejected here are readable on inhibiting angiogenesis without any further recitation of a disorder to be treated. Inhibiting angiogenesis in an otherwise

healthy tissue is confusing and unclear. It is unclear and indefinite as to why such angiogenesis inhibition would be necessary. Clarification is required.

(2) In claim 9, the ligand "H" is confusing. It could mean hydrogen or acetonylhydroxamic moiety. It is unclear which is intended without further clarification.

(3) In claim 9, "derivatives thereof" is unclear. How much derivation is within the scope of the invention? Is it mere substitution on the main structure, or can the main structure be materially changed?

(4) The same "derivative thereof" issue is found in claim 10.

Claims 4-10, 25, 27-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for administering an effective amount of the vanadocene compounds of claim 4 directly to a tissue in need of angiogenesis inhibition, does not reasonably provide enablement for other modes of administration such as oral administration or modes of administration wherein the vanadocene does not make direct contact with the tissue in need of angiogenesis immediately upon administration. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use or practice the invention commensurate in scope with these claims.

It would appear that the vanadocene compounds of claim 4 are non-selective angiogenesis inhibiting compounds. The claims are written so that said compounds are

administered to any subject having non-cancerous tissue (claim 4) or any subject having other tissues such as vascular tissue, coronary artery, retina, blood vessel (dependent claims). The claims do not require that these tissues be in need of angiogenesis inhibition. This is problematic because the state of the art involving angiogenesis recognizes that angiogenesis is an important natural process occurring in the body, both in health and disease. Angiogenesis occurs in a healthy body for healing wounds, restoring blood flow after injury, and during reproductive cycles and pregnancy in females, just to mention a few examples. The relative skill of those in the art is quite high because inhibiting angiogenesis requires plenary medical education and training to be able to practice and administer medication. Unpredictability in the art is also quite high, because the ultimate result would be fraught with unpredictability in a systemic administration of an angiogenesis inhibitor, i.e. not directly targeted and applied to the diseased tissue area, due to the non-specific action of the angiogenesis inhibitor. Insufficient angiogenesis in non-target tissues risks undesirable tissue death. The amount of direction or guidance provided by applicant is very general. On specification page 11, lines 11-27, various modes of administration such as oral, IV, IM, topical, subcutaneous are disclosed. No guidance as to the practice of the full scope of the claims (any mode of administration to any tissue) is provided. It is not disclosed how to avoid insufficient angiogenesis in tissues where angiogenesis inhibition is not desirable when administering systemically or not directly onto the tissue in need of angiogenesis

inhibition. In vitro angiogenesis inhibition is disclosed in specification Example 2, but such disclosure adds little to the scope of enablement issue here, which is directed to in vivo angiogenesis inhibition in unspecified (i.e. diseased and in need of angiogenesis inhibition or not diseased) tissues via any mode of administration. Therefore, taken as a whole, one skilled in the art would be faced with an amount of experimentation that would be undue to practice the claimed invention to full extent of its present scope.

For these reasons, all claims must be rejected.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620, effective February 3, 2004.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Thurman Page, can be reached on (571)272-0602, effective February 3, 2004.

The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

JOHN PAK
PRIMARY EXAMINER
GROUP 1600